

SMAR.P-001
Patent Application

REMARKS

This amendment is filed along with an RCE application. Applicants requests a three month extension of time to respond to the Official Action in the parent case, and includes the appropriate fee.

Claims 4 and 6-13 have been cancelled and claims 14-43 have been added. Claim 14 is substantially the same as original claim 2. The dependent claims recite a specific assay technique (claim 15), and additional indicator which can be derived from the test results (claim 16) and specific combinations of results and the conditions with which they are associated. This later group of claim is supported in the tabular data provided.

Responding to specific issues in the Office Action mailed December 5, 2001, Applicants note that the drawings were submitted with the previous office action were not intended to be included in the application, but merely to provide a graphical representation to facilitate consideration of the tabular data. Furthermore, as previously indicated, Applicants will address the draftsman's concerns with the drawings upon receipt of an indication of allowance.

The Examiner rejected method claims 4 and 6-8 under 35 USC § 102 as anticipated by Lindgren et al. As was previously noted, the Lindgren article performs the same tests as called for in the present method, **but is wholly lacking in any indication that the results of the tests can be used in combination.** Using the same basic methods for obtaining test results does not mean that the entire method, including the way in which the data is utilized, is the same. The Lindgren article does not teach that "the presence of H,K-ATPase antibodies, Helicobacter pylori antibodies, and pepsinogen I concentration **are compared between themselves and in relation to the respective values** of H,K-ATPase antibodies, Helicobacter pylori antibodies, and pepsinogen concentration of a normal population" as recited in claim 14. Therefore, Applicants respectfully submit that the Lindgren reference does not teach each and every element of the newly submitted method claim 14, and therefore cannot be deemed to anticipate this claim or any claim dependent thereon.

The Examiner also rejected kit claims 9-13 as obvious over the Lindgren. The Examiner asserts that Lindgren's teaching of using all three tests on one set of samples makes

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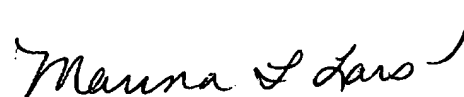
construction of a kit obvious, but he does not really say why. In the Official Action of December 5, 2001, the Examiner states that "it must be remembered that assembling a kit is not for the purpose of repeating the same data as Applicants argue." Applicants respectfully submit that the allegedly obvious kit must be assembled for some purpose, or there would be no motivation to make the kit. If this purpose is not for purposes of repeating the study described in the reference (which concludes that only one of the tests is of much utility for purpose stated), then the Examiner must come forward with some other purpose. This has not been done. Therefore Applicants submit that the rejection does not meet the statutory requirements and should be withdrawn.

The Examiner rejected kit claims 9-13 under 35 USC § 103 as obvious over Oksanen in view of Ma et al. These references each teach tests for two of the three indicators specified in new claim 39. By the Examiner's own interpretation, the tests are for different patient populations (predicting normal gastric mucosa versus testing of patients with pernicious anemia). Neither test, however, discloses anything about using the test results in combination as a means for classifying the type of gastritis. In Oksanen, the comparison made is solely between a normal and an abnormal gastric mucosa, with no resolution of the mucosal location or the type of gastritis. Similarly, Ma et al. reports results from two types of test, but is concerned with the possible existence of related epitopes on H. pylori and H,K-ATPase. No cross reactions were found. Ma et al. does not discuss or suggest the ability of the tests to function in concert to provide an indication of the type of gastritis. Thus, there is no specific suggestion for making a combination of the three types of reagents into a single kit -- there is no teaching of any combined or synergistic use of the three reagents, nor any teaching that optimization of diagnostic technique (which the Examiner advances as a motivation or reason for making the claimed kit) would result from doing multiple tests with the three recited reagents. Thus, there is no obvious reason why a person skilled in the art would be motivated to assemble the reagents into a kit.

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For the foregoing reasons, Applicants submit that the claims of this application are in form for allowance. Favorable reconsideration and allowance of all claims are respectfully urged.

Respectfully submitted,



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